K050185

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MAY 26 2005

510(k) Summary of Safety and Effectiveness Information

5 Fr SL PowerHohn™ and PowerLine™ Catheters

6.1 Submitter Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 5541
Fax Number:	(801) 595-4903
Contact Person:	Charles Morreale
Date of Preparation:	January 17, 2005

6.2 Device Name

Device Name:	PowerHohn™ and PowerLine™ Catheter
Trade Name:	PowerHohn™ and PowerLine™ Catheter
Common/Usual Name:	Central Venous Catheter
Classification Name:	Class II, 80 LJS – Long Term Intravascular Catheter
Classification Panel:	General Hospital

6.3 Predicate Device(s):

Device Name:	PowerPICC™ Catheter
Trade Name:	PowerPICC™ Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Class II, 80 LJS – Long Term Intravascular Catheter
Classification Panel:	General Hospital
Premarket Notification:	K033389, Substantial Equivalence: April 14, 2004

Device Name:	Broviac® Catheter
Trade Name:	Broviac® Catheter
Common/Usual Name:	Central Venous Catheter
Classification Name:	Class II, 80 LJS – Long Term Intravascular Catheter
Classification Panel:	General Hospital
Premarket Notification:	K830256, Substantial Equivalence: March 1, 1983

6.4 Device Description

- The **PowerHohn and PowerLine Catheters** are open-ended radiopaque polyurethane catheters.
- Catheter size is 5 Fr SL with 50 cm usable length.
- The catheter has a reverse taper design.
- Catheter shaft tubing is marked with depth indicators, with "0" indicated to serve as a reference for the catheter insertion point.
- **PowerHohn and PowerLine Catheters** are provided in sterile tray configurations.
- Purple colorants were added to the catheter materials to provide the catheter with an appearance that allows the end user to differentiate the **PowerHohn and PowerLine** as power injectable from other central venous catheters.
- The molded hub is labeled to identify the catheter as **PowerHohn and PowerLine.**
- The catheter extension leg and clamp are labeled with information to facilitate proper use of the device.

6.5 Intended Use

PowerHohn™ and PowerLine™ Catheters are indicated for short or long term access to the central venous system. They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal and power injection of contrast media. The maximum recommended infusion rate is 5cc/sec. The maximum pressure of power injectors used with the PowerHohn and PowerLine catheters may not exceed 300 psi.

6.6 Technological Characteristics Summary

New device is compared to Marketed Device

Yes.

Does the new device have the same indication statement?

Yes. However, the Indications For Use were expanded to provide instructions for chest placement, percutaneous introduction and tunneling techniques for central venous catheters.

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. deciding may consider impact on safety and effectiveness)?

No, the differences do not alter the intended use of the device.

Does the new device have the same technological characteristics, e.g. design, material, etc.?

Yes. The PowerHohn and PowerLine catheters are identical to the PowerPICC catheter in terms of catheter design, materials, color (purple), and manufacture, with the exception of the addition of a SureCuff® Tissue Ingrowth Cuff to the PowerLine Catheter and an optional VitaCuff® Antimicrobial Cuff to the PowerHohn Catheter. The basic fundamental scientific technology of the catheter has not changed.

Could the new characteristics affect safety or effectiveness?

Yes. The new characteristics could affect safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?

No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters*, dated 3/16/95, and relevant ISO 10555 Standards were used to determine the appropriate methods for evaluating the modified device's performance.

There are no new materials therefore, no new biocompatibility is required.

Are performance data available to assess effects of new characteristics?

Yes. Verification testing was performed according to protocols based on the above-referenced guidance document recommendations and additional standards.

Do performance data demonstrate equivalence?

Yes. Performance data gathered in design verification testing demonstrated that the **PowerHohn and PowerLine Catheter** is substantially equivalent to the predicate devices.

Conclusion
The **PowerHohn and PowerLine Catheters** met all the predetermined performance criteria of design verification evaluations and is substantially equivalent to the predicate devices.

6.7 Conclusion

The **PowerHohn and PowerLine Catheters** meet all the acceptance criteria of the testing performed and, based on FDA's decision tree, is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 2005

Mr. Charles Morreale
Senior Manager Quality Systems/ Regulatory Affairs
Bard Access Systems, Incorporated
5425 West Ameila Earhart Drive
Salt Lake City, Utah 84116

Re: K050185
Trade/Device Name: 5 Fr SL PowerHohn and PowerLine Catheters
Regulation Number: 880.5970
Regulation Name: Percutaneous Implanted Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: April 1, 2005
Received: April 8, 2005

Dear Mr. Morreale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

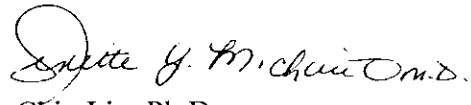
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050185
1 OF 1

PowerHohn™ and PowerLine™ Catheters
510(k) Premarket Notification

STATEMENT OF INDICATION FOR USE

510(k) Number (if known): **K050185**

Device Name: **5 Fr SL PowerHohn and PowerLine Catheters**

Indications For Use:

PowerHohn and PowerLine Catheters are indicated for short or long term access to the central venous system. They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal and power injection of contrast media. The maximum recommended infusion rate is 5cc/sec. The maximum pressure of power injectors used with the PowerHohn and PowerLine catheters may not exceed 300 psi.

Prescription Use ___X_____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner for MW

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K050185